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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,546	10/30/2003	David W. Wynn	MCP-5015	7575
27777	7590	01/25/2008		
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			EXAMINER YOUNG, MICAH PAUL	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			01/25/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/697,546	<b>Applicant(s)</b> WYNN ET AL.	
	<b>Examiner</b> Micah-Paul Young	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4 and 13-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 13-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/30/07 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3, 13-19, 21, 23, 24 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Hsiao et al (USPN 5,885,616 hereafter '616). The claims are drawn to a dosage form comprising an immediate release portion of a NSAID and an extended release portion of an NSAID comprising a coating where the coating comprising insoluble polymers and enteric polymers.

4. The '616 patent teaches a dosage form comprising an immediate release drug portion and a controlled release drug portion (abstract). The drug includes acetaminophen (col. 5, lin. 15-20). The coating composition covering the sustained release compartment comprising multiple polymers, specifically an enteric polymer and an insoluble polymer (col. 6, lin. 35-55). The insoluble polymers include cellulose ethers, esters and acrylic resins such as Eudragit RL, and

RS (col. 6, lin. 40-44). The enteric polymers include acrylate polymers such as Eudragit L and S (col. 6, lin. 50-54). The ratio of water insoluble polymer to enteric polymer in the sustained release layer is 28:5, or 5.6:1 well within the limits of the instant claims. The second drug component comprising from 5-30% of the total dosage from (col. 9, lin. 11-15). The active ingredient is present in the first or second compartments in a concentration as low as 70%, where the ratio of the first to second drug compartments measure 4:1 to 1:4 by weight percentage (example 1, col. 8, lin. 28-34). The dosage form release up to 24 hours (TABLE IV-VII). These disclosures render the claims anticipated.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-4, and 13-35 rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Shah et al (USPN 6,126,969 hereafter '969) in view of Hsiao et al

(USPN 5,885,616). The claims are drawn to a dosage form comprising an immediate release and sustained release portion, where the dosage form has a liquid vehicle forming a liquid suspension.

8. The '969 patent teaches a dosage form comprising an immediate release portion and an extended releasing portion (abstract). The dosage form comprises sweeteners and other excipients (col. 7, lin. 15-30). The extended release portion comprises coated core particles where the coating comprises an enteric polymer (col. 5, lin. 15-20; examples). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lin. 40-58). The active agents include various well-known drugs including acetaminophen (tables). The acetaminophen is present in each phase in a concentration of approximately 41.5 % (table 2). Another embodiment of the invention has the coated particles in a concentration of approximately 20.79% (table 1). The formulation comprises polyethylene glycol (Table 1 and 2). Regarding the therapeutic effect of the dosage form, it is the position of the Examiner that such limitations are inherent features of the composition. Regarding the liquid suspension limitation, the '969 patent is suggestive that the formulation can be dispersed in water in order to form a suspension (col. 4, lin. 15-17). The reference is however is not explicit about the exact structure of the liquid suspension; it is the position of the Examiner that the concentrations would be similar to those of the controlled release formulation. It is the position of the Examiner that these concentrations represent an optimization of ranges and are not inventive barring a showing of unexpected results.

9. The reference is silent to the ratio of the instant claims. As discussed above the '616 patent discloses an immediate and sustained release formulation comprising a sustained release

coating comprising an insoluble polymer and an enteric polymer in a ratio from 1:4 to 4:1 within the limits of the instant claims (col. 8, lin. 28-34). The artisan of ordinary skill would be motivated to use the coating composition of the '616 patent in order provide improved sustained release of the active agents.

10. With these aspects in mind it would have been obvious to combine the sustained release coated particles of the '616 patent into the liquid suspension of the '969 patent. It would have been obvious to combine the particles into the suspension of the '969 with an expected result of a controlled release liquid suspension with improved release over a 24 hour period.

#### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1-4, and 13-35 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 6:00-3:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
MP Young

Micah-Paul Young  
Examiner  
Art Unit 1618

  
MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER